

Minutes of TES Weekly Status Meeting (PM-8451)
March 10, 2003
Page 1 of 3

Participants

Philip Morris

Candace Adams

Valerie King

Robin Kinser

Bettie Nelson

Jan Oey

Hans-Juergen Roethig

Mohamadi Sarkar

MDS

Kimberly Prchal

Covance

Lisa Geishirt

Mary Larson

Jill Schultz

Mary Westrick

The following items were discussed:

Approval of 03/03/03 Minutes

Minutes from 03/03/03 were approved

Stratification Cells

There were no comments on the stratification information.

Site Performance Markers

Table indicates that no samples have been analyzed for nicotine. Mark Bentley contacted Robin to inform her that the aglycone assay for nicotine and metabolites has been run on 700 samples. The samples will then be assayed using the total nicotine and metabolites assay. Robin requested that the table of site performance markers be revised to reflect the two steps for the assays. **ACTION: J. Schultz**

Philip Morris would also like a more detailed spreadsheet regarding the plan for sample analysis (e.g., no. of batches to be analyzed each week). An analytical conference call will be scheduled monthly. Robin indicated that it would most likely be another week before MDS starts providing updates.

ACTIONS:

M. Bentley and B. Tetlow to prepare spreadsheet and send to J. Schultz by 03/14/03.

J. Schultz to schedule analytical conference call (early April).

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Minutes of TES Weekly Status Meeting (PM-8451) - Continued
March 10, 2003
Page 2 of 3

Topography Downloads

J. Schultz indicated that the etrials report for the no. of topography files downloaded was unavailable. The problem was not related to the issue that Eric Larson was correcting with the sites (contacting sites to make sure their computer is set up to allow the topography data to be downloaded to etrials).

ACTIONS:

J. Schultz to follow up with etrials and report back to Philip Morris.

E. Larson to provide update on the no. of sites contacted to ensure computers are set up correctly to allow topography files to be downloaded.

Recruitment for Low Tar Group

M. Larson reported that she had contacted Joel Monsky (Partnership for Shared Marketing) regarding the database he has from credit card purchases. The database can be queried by age, brand, gender, zip codes, etc. Mary will prepare a list of zip codes that are surrounding the sites as we don't want to query individuals that are too far from the sites. Only sites that are currently open will be used. Mary indicated that it appeared that Mr. Monsky worked out of his home and wanted to make sure that Philip Morris was comfortable using his services. Robin indicated that the contact was recommended from within Philip Morris but that they would check again. Mary indicated that the database would be queried by brand name as the list of UPC codes is not complete. Philip Morris expressed concern as brand names can include several tar categories (hard vs soft pack). We would need to make sure the brand names in the database are specific enough so individuals that smoke the cigarettes in the desired tar category are contacted.

Postcard will contain IRB-approved picture of leaf. Language will be generic and similar to language already approved by IRB.

ACTIONS:

J. Schultz to send workscope change to Philip Morris and obtain authorization to proceed.

Mary Larson to send example of postcard to be used to Philip Morris for approval.

Sample Banking

Philip Morris reported that one of the biomarkers may be absorbed into the container (~30%). May be due to a bad lot of plastic. Philip Morris will also continue to monitor literature as the samples may not be stable when the year has passed. Further discussions will take place when more information becomes available.

Cell Enrollment

Tulane will not have IRB approval until the 3rd week in March. VCU will start advertising next week.

Minutes of TES Weekly Status Meeting (PM-8451) - Continued
March 10, 2003
Page 3 of 3

Letter of Administrative Change (LOAC)

Wording from Philip Morris for the LOAC is not yet available. Proposed language provided by their legal group was not acceptable. May be another week before language is available.

ACTION: Philip Morris to provide wording for LOAC.

TES Time Line

Philip Morris would like recruitment to be completed in April; however, Tulane will not have IRB approval for another week. Hans questioned why the final questionnaire, CRF, and topography data transfers would not occur until Nov. 2003 or Jan 2004. These dates will depend on when recruitment is complete. **ACTION: M. Larson to review time line.**

Data Transfers

Philip Morris asked if Eric Larson would be providing information to MDS that explains the files that are being transferred. **ACTION: M. Westrick to confirm with E. Larson.**

Next Call

Date: March 17, 2003

Time: 1:00 pm CT/2:00 pm ET

Password: CCS

Conference Leader: Jill Schultz

Toll Free No.: 888-384-8977 (domestic)

484/630-7995 (international, if needed)

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